

EXHIBIT B-9

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October 6, 2015

Via e-mail

Andrew N. Faes
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112

RE: In re: Ethicon, Inc. Pelvic Repair System
Particle Loss 30(b)(6) Document Responses

Dear Andy:

The following is by way of follow-up to our discussions and correspondence regarding the document portion of Plaintiffs' June 25, 2015 30(b)(6) Notice regarding particle loss issues (the "Notice") and subsequent amendments thereto.

As we discussed, Ethicon agreed to provide additional specificity with respect to documents it referenced in its response to the Notice. The following information is based upon a reasonable and good faith investigation and takes into account the parties' good faith efforts to meet and confer to prioritize and narrow the scope of Plaintiffs' original document requests in the Notice. These are not intended to be a comprehensive listing of materials that are responsive, but rather, a good faith attempt to identify responsive materials that we have identified within the production pursuant to reasonable searches. In some instances, as previously discussed, we conducted additional searches to supplement the production and identified the documents resulting from such additional searches and productions in the following lists.

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1. Documents Related to 10 Returned TVT-O Products

Plaintiffs requested communications and documents reflecting analyses or testing of ten returned TVT-O products. Based on our investigation, the return of these ten products resulted in the creation of the following complaints: complaint number CC1007005 is associated with complaint file 10100122655. Complaint number CC1007047 is associated with four complaint files: 10100124603; 10100124604; 10100124605; and 10100124606. Complaint number CC1007048 is associated with two complaint files: 10100124625 and 1010012463.

Complaint 10100122655 and Communications Referencing Complaint 10100122655:

ETH.MESH.13013289 – ETH.MESH.13013309
ETH.MESH.19023088 – ETH.MESH.12023095
ETH.MESH.19134089 – ETH.MESH.19134089
ETH.MESH.02656825 – ETH.MESH.02656834
ETH.MESH.12943538
ETH.MESH.12943537
ETH.MESH.12943536
ETH.MESH.13204537
ETH.MESH.13204520 – ETH.MESH.13204521
ETH.MESH.13204535 – ETH.MESH.13204536
ETH.MESH.13204551 – ETH.MESH.13204552
ETH.MESH.13210344 – ETH.MESH.13210346
ETH.MESH.13206811
ETH.MESH.03500957 – ETH.MESH. 03500958
ETH.MESH.03500966 – ETH.MESH.03500970
ETH.MESH.03497848 – ETH.MESH. 03497850
ETH.MESH.03497863 – ETH.MESH.03497865
ETH.MESH.03497834 – ETH.MESH.03497835
ETH.MESH.13206205 – ETH.MESH.13206208
ETH.MESH.04101810 – ETH.MESH.04101813
ETH.MESH.01745568 – ETH.MESH.01745572
ETH.MESH.01068905 – ETH.MESH.01068906
ETH.MESH.13204538 – ETH.MESH.13204540
ETH.MESH13204510
ETH.MESH.13204511
ETH.MESH.13204512
ETH.MESH.13204513
ETH.MESH.13204514
ETH.MESH.13204515

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ETH.MESH.13204516
ETH.MESH.13204517
ETH.MESH.13204518
ETH.MESH.13204519
ETH.MESH.13204525
ETH.MESH.13204526
ETH.MESH.13204527
ETH.MESH.13204528
ETH.MESH.13204529
ETH.MESH.13204530
ETH.MESH.13204531
ETH.MESH.13204532
ETH.MESH.13204533
ETH.MESH.13204534
ETH.MESH.13204541
ETH.MESH.13204542
ETH.MESH.13204543
ETH.MESH.13204544
ETH.MESH.13204545
ETH.MESH.13204546
ETH.MESH.13204547
ETH.MESH.13204548
ETH.MESH.13204549
ETH.MESH.13204550

**Complaint 10100124603 and Communications Referencing Complaint
10100124603:**

ETH.MESH.13013970 – ETH.MESH.13013976
ETH.MESH.19023349 – ETH.MESH.19023353
ETH.MESH.19134157
ETH.MESH.02656888 – ETH.MESH.02656892
ETH.MESH.13206148 – ETH.MESH.13206149
ETH.MESH.12943671
ETH.MESH.13226456
ETH.MESH.13226457
ETH.MESH.13206205 – ETH.MESH.13206208
ETH.MESH. 01068907
ETH.MESH.01068908
ETH.MESH.13206144 – ETH.MESH. 13206147

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**Complaint 10100124604 and Communications Referencing Complaint
10100124604:**

ETH.MESH.13013977 – ETH.MESH.13013983
ETH.MESH.19023354 – ETH.MESH.19023358
ETH.MESH.19134158
ETH.MESH.02656893 – ETH.MESH.02656897
ETH.MESH.13206167 – ETH.MESH.13206168
ETH.MESH.12943672
ETH.MESH.13206205 – ETH.MESH.13206208
ETH.MESH. 01068907
ETH.MESH.01068908
ETH.MESH.13206144 – ETH.MESH. 13206147
ETH.MESH.13225324
ETH.MESH.13225325

**Complaint 10100124605 and Communications Referencing Complaint
10100124605:**

ETH.MESH.13013984 – ETH.MESH.13013989
ETH.MESH.19023359 – ETH.MESH.19023364
ETH.MESH.19134159
ETH.MESH.02656898 – ETH.MESH.02656902
ETH.MESH.13206175 – ETH.MESH.13206176
ETH.MESH.13226456
ETH.MESH.13226457
ETH.MESH.13206205 – ETH.MESH.13206208
ETH.MESH. 01068907
ETH.MESH.01068908
ETH.MESH.13206144 – ETH.MESH. 13206147

**Complaint 10100124606 and Communications Referencing Complaint
10100124606:**

ETH.MESH.13013990 – ETH.MESH.13013996
ETH.MESH.19023365 – ETH.MESH.19023369
ETH.MESH.19134160
ETH.MESH.02656903 – ETH.MESH.02656907
ETH.MESH.13206186 – ETH.MESH.13206187
ETH.MESH.12943673
ETH.MESH. 01068907
ETH.MESH.01068908

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ETH.MESH.13206182 – ETH.MESH.13206185
ETH.MESH.13206214 – ETH.MESH.13206218
ETH.MESH.13225744
ETH.MESH.13225745

Complaint 10100124625 and Communications Referencing 10100124625:

ETH.MESH.13014005 – ETH.MESH.13014011
ETH.MESH.19023376 – ETH.MESH.19023380
ETH.MESH.19134162
ETH.MESH.02656913 – ETH.MESH.02656917
ETH.MESH.13206229 – ETH.MESH.13206230
ETH.MESH. 12943675
ETH.MESH.04101014– ETH.MESH.04101015
ETH.MESH.01068907
ETH.MESH.01068908
ETH.MESH.13206144 – ETH.MESH. 13206147
ETH.MESH.13206223 – ETH.MESH.13206226
ETH.MESH.13206231 – ETH.MESH.13206234
ETH.MESH.13226201
ETH.MESH.13226202

Complaint 10100124623 and Communications Referencing 10100124623:

ETH.MESH.13014000 – ETH.MESH.13014004
ETH.MESH.19023371– ETH.MESH.19023375
ETH.MESH.19134161
ETH.MESH.02656908 – ETH.MESH.02656912
ETH.MESH.13206158 – ETH.MESH.13206159
ETH.MESH.13226456
ETH.MESH.13226457
ETH.MESH.03500461 – ETH.MESH.03500464
ETH.MESH. 01068907
ETH.MESH.01068908
ETH.MESH.13206144 – ETH.MESH. 13206147

2. Additional Complaints Reporting Particles or Foreign Material:

Plaintiffs requested all complaints and reports received by Defendants reporting particles or foreign material in TVT product or packaging.

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It is Defendants' understanding that such reports would be part of Ethicon's complaint files. For a list of all prior production installments containing complaint files from CHATS Remetrex and Seibel, Defendants refer Plaintiffs to Defendants' Initial Responses and Objections to Request No. 2. Defendants' production of complaint files is current through April 21, 2015.

Plaintiffs may identify complaint files reporting particles or foreign materials in the product or packaging by searching the document production installments referenced above.

Associated Communications with Healthcare Providers:

Plaintiffs requested correspondence sent by or received by defendants from healthcare providers regarding reports of particles or foreign material in TVT packaging or product.

It is Defendants' understanding that correspondence sent by or received by Defendants from healthcare providers regarding complaints of particles or foreign material in TVT packaging or product would be expected to be part of Ethicon's complaint files.

Examples of such communications found in complaint files include:

ETH.MESH.03499583
ETH.MESH.03476684 – ETH.MESH.03476685
ETH.MESH.12933804
ETH.MESH.03499570

3. Cost of Potential Recall of Any TVT Lot Number(s)

Plaintiffs requested documents discussing and reflecting analysis of the cost involved with any potential recall action of any TVT lot number(s).

Relevant Central Source: The following is a collection of internal documentation related to Ethicon's voluntary recall of certain TVT products manufactured by Medscand in September 2000. The file includes Product Recall/Market Withdrawal/Field Correction Reports which include the estimated cost of the recall to the company, including the lost sales volume, administrative cost, product replacement cost, and product destruction costs.

TVT Recall Binder: ETH.MESH.08687546 – ETH.MESH.08687713

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4. Scientific or Medical Analyses Related to Particles or Foreign Matter

Plaintiffs requested any scientific or medical analyses performed by Defendants on potential patient consequences of particles or foreign matter in TVT products or packaging and communications regarding such analyses.

Clinical Expert Reports:

ETH.MESH.01784823 – ETH.MESH.01784828

ETH.MESH.01070192 – ETH.MESH.01070209

PSE Accession No. 02-0579 (14 Day Rabbit Study): ETH.MESH.02614284 –
ETH.MESH.02614316

Risk Assessment Summary for Products in the Gynecare TVT-Obturator and TVT
Abbrevio Systems: ETH.MESH.10703813 – ETH.MESH.10703828

Risk Assessment Summary for Products in the Gynecare TVT and Gynecare TVT
Exact Systems: ETH.MESH.10703794 – ETH.MESH.10703810

Examples of relevant complaint files and associated communications addressing
potential patient consequences of particles or foreign material:

ETH.MESH.19984722 – ETH.MESH.1994723

ETH.MESH.13216087

ETH.MESH.13205871 – ETH.MESH.13205872

ETH.MESH.03490771

ETH.MESH.12931604

ETH.MESH.03499904 – ETH.MESH.03499905

Other examples may be identified by searching previously produced complaint files.

5. Documents Reflecting Investigation, Analyses, Conclusions, and Corrective and Preventative Actions Regarding Particles or Foreign Material in Products or Packaging of TVT Products

Plaintiffs requested documents and communications reflecting investigation, analyses, conclusions, and corrective and preventive actions regarding particles or foreign material in TVT products or packaging.

CAPA #130022:

ETH.MESH.15137959 – ETH.MESH.15137967

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ETH.MESH.15137968
ETH.MESH.15137969 –ETH.MESH.15137978;
ETH.MESH.15137979
ETH.MESH.15137980 – ETH.MESH.15137983
ETH.MESH.15137988 – ETH.MESH.15137989
ETH.MESH.15137986 – ETH.MESH.15137987
ETH.MESH.15137984 – ETH.MESH.15137985

Examples of NCR Summary Reports Referencing “Particle” or “Foreign Matter” or “Foreign Body”:

ETH.MESH.05618965 – ETH.MESH.05618968 (NCR08-00844)
ETH.MESH.15146634 – ETH.MESH.1516640 (NCR13-01136)
ETH.MESH.15146599 – ETH.MESH.15146606 (NCR13-00712)
ETH.MESH.15146479 – ETH.MESH.15146484 (NCR12-10293)
ETH.MESH.15146255 – ETH.MESH.15146261 (NCR12-05143)
ETH.MESH.15146512 – ETH.MESH.15146518 (NCR12-10960)
ETH.MESH.15147239 – ETH.MESH.15147248 (NCR14-01107)
ETH.MESH.15147103 – ETH.MESH.15147111 (NCR13-08752)
ETH.MESH.15146851 – ETH.MESH.15146854 (NCR13-05799)
ETH.MESH.05618706 – ETH.MESH.05618710 (NCR07-09219)
ETH.MESH.05620997 – ETH.MESH. 05621002 (NCR11-02220)
ETH.MESH.05620848 – ETH.MESH.05620851 (NCR10-10411)
ETH.MESH.05620858 – ETH.MESH.05620889 (NCR11-00099)
ETH.MESH.05620789 – ETH.MESH.05620794 (NCR10-08653)
ETH.MESH.05618551 – ETH.MESH.05618555 (NCR07-07434)
ETH.MESH.05618711 – ETH.MESH.05618718 (NCR07-09366)
ETH.MESH.05619084 – ETH.MESH.05619088 (NCR08-02694)
ETH.MESH.05620795 – ETH.MESH.05620798 (NCR10-08795)
ETH.MESH.05618928 – ETH.MESH.05618933 (NCR08-00306)
ETH.MESH.05618268 – ETH.MESH.05618271 (NCR07-05118)
ETH.MESH.05619130 – ETH.MESH.05619135 (NCR08-03464)
ETH.MESH.05618910 – ETH.MESH.05618915 (NCR08-00125)
ETH.MESH.05621123 – ETH.MESH.05621127 (NCR11-06152)
ETH.MESH.05620936 – ETH.MESH.05620939 (NCR11-01241)
ETH.MESH.05621228 – ETH.MESH.0561233 (NCR11-09676)
ETH.MESH.05621244 – ETH.MESH.05621248 (NCR11-10471)
ETH.MESH.05619613 – ETH.MESH.05619618 (NCR09-00230)
ETH.MESH.05621427 – ETH.MESH.05621432 (NCR12-05143)
ETH.MESH.05620371 – ETH.MESH.05620382 (NCR10-02107)
ETH.MESH.05618340 – ETH.MESH.05618345 (NCR07-05799)
ETH.MESH.05620216 – ETH.MESH.05620219 (NCR10-00135)

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ETH.MESH.05620419 – ETH.MESH.05620422 (NCR10-02590)
ETH.MESH.05620799 – ETH.MESH.05620803 (NCR10-08796)
ETH.MESH.05620172 – ETH.MESH.05620179 (NCR09-11362)
ETH.MESH.05620914 – ETH.MESH.05620918 (NCR11-00965)
ETH.MESH.05618304 – ETH.MESH.05618309 (NCR07-05236)
ETH.MESH.05620410 – ETH.MESH.05620413 (NCR10-02418)
ETH.MESH.05618374 – ETH.MESH.05618379 (NCR07-05860)
ETH.MESH.05618922 – ETH.MESH.05618927 (NCR08-00176)
ETH.MESH.05621043 – ETH.MESH.05621043 (NCR11-03249)
ETH.MESH.05621241 – ETH.MESH.05621243 (NCR11-10407)
ETH.MESH.05620760 – ETH.MESH.05620763 (NCR10-08210)
ETH.MESH.05619282 – ETH.MESH.05619287 (NCR08-06553)
ETH.MESH.05620716 – ETH.MESH.05620719 (NCR10-07543)
ETH.MESH.05620961 – ETH.MESH.05620966 (NCR11-01734)
ETH.MESH.05621128 – ETH.MESH.05621132 (NCR11-06171)
ETH.MESH.05620605 – ETH.MESH.05620608 (NCR10-05393)
ETH.MESH.05621164 – ETH.MESH.05621171 (NCR11-08123)
ETH.MESH.05619701 – ETH.MESH.05619706 (NCR09-01192)
ETH.MESH.05620431 – ETH.MESH.05620435 (NCR10-02662)
ETH.MESH.05620264 – ETH.MESH.05620266 (NCR10-00429)

Communications and Other Documents Reflecting Investigation, Analyses, Conclusions, or Corrective and Preventative Actions Regarding Particles or Foreign Matter:

The following Bates ranges are examples of documents within the production reflecting investigation, analyses, conclusions, or corrective and preventative actions regarding particles or foreign matter in products or packaging of TVT products:

TVT Technical File: ETH.MESH.00309254 – ETH.MESH.00309350

TVT-Base and TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis:
ETH.MESH.01784779 – ETH.MESH.01784782

Example of Corrective/Preventive Action Audit Summary: ETH.MESH.05961543 –
ETH.MESH.05961548

Other Communications, Powerpoints, and Meeting Minutes:
ETH.MESH.13204333 – ETH.MESH.03204334
ETH.MESH.13204335
ETH.MESH.02248778
ETH.MESH.14117074 – ETH.MESH.14117075

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ETH.MESH.13886781 – ETH.MESH.13886782
ETH.MESH.13883268 – ETH.MESH.13883275
ETH.MESH.22754103
ETH.MESH.14708810
ETH.MESH.14708986
ETH.MESH.22815634 – ETH.MESH.22815636

Additional documents pertaining to the above issue may be found in the following custodial and central sources, as well as elsewhere in the production: Product Lifecycle Management (PLM) System; Jamil Jaccard; Shalot Palmer (Shay Armstrong).

Defendants also refer Plaintiffs to the categories and examples of documents previously described in sections 1, 2 and 4 for additional materials reflecting investigation, analyses, and conclusions regarding particles or foreign material in TVT products or packaging.

6. Documents Reflecting Inspection, Acceptance, and Rejections of TVT Products:

Plaintiffs requested documents reflecting inspections, acceptance, and rejections of TVT products based on relevant specifications and operating procedures.

The Design History Records for the following lots, requested by Plaintiffs in their July 29, 2015 correspondence, have been produced:

Lot 3405428: ETH.MESH.22734884 – ETH.MESH.22734937
Lot 3413118: ETH.MESH.22734721 – ETH.MESH.22734776
Lot 3398077: ETH.MESH.22734663 – ETH.MESH.22734720
Lot 3413119: ETH.MESH.22734777 – ETH.MESH.22734833
Lot 3413121: ETH.MESH.22734834 – ETH.MESH.22734883
Lot 3389752: ETH.MESH.22734560 – ETH.MESH.22734609
Lot 3389753: ETH.MESH.22734610 – ETH.MESH.22734662

NCR Summary Reports responsive to this request can be found in Productions 83, 219 and 223. Defendants have identified examples of Summary Reports produced from the Product Life Management System related to particles or foreign material in products or packaging of TVT products above, though Plaintiffs may search the productions for additional Reports.

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Batch Reviews for individual lots associated with a complaint may be found within individual complaint files. See, for example, ETH.MESH.12943675 and ETH.MESH.03477858.

7. Documentation Regarding Returned TVT Complaint Samples

Plaintiffs requested documentation regarding returned TVT complaint samples, including documentation of testing and analyses, receipt, storage and disposal of returned samples.

Documentation of product returns and analysis of returned products, including Functional and Visual Test Results, is contained within individual complaint files.

The following company procedures govern the decontamination, testing, and analysis of returned samples, as well sample retention and disposal:

PR-000118: ETH.MESH.08462125 – ETH.MESH.08462148
EPG08: ETH.MESH.13923420 – ETH.MESH.13923425
PR566-011: ETH.MESH.03745001 – ETH.MESH.03745016

Pursuant to Ethicon's Franchise Procedure for Product Complaint Management, PR-000118, "[r]eturned complaint samples not related to reportable adverse events may be discarded upon completion of investigation . . ." Information regarding return of product samples and complaint closure may be found in individual complaint files.

8. Operating Procedures:

Plaintiffs requested historical versions of certain operating procedures and specifications used by Defendants for acceptance or rejection of TVT products based on particles or foreign material in the product or packaging, as well as associated communications regarding changes to those documents.

TM403-166: Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products

See Appendix 1 for production information.

Examples of Communications Referencing Changes to TM403-166:

ETH.MESH.14449990 – ETH.MESH.14449992

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EMQD10: Common Defects

Revision A: ETH.MESH.22708044
Revision B: ETH.MESH.22708045
Revision C: ETH.MESH.22708046
Revision D: ETH.MESH.14144580
Revision E: ETH.MESH.13862886
Revision F: ETH.MESH.01310202
Revision G: ETH.MESH.22708048 – ETH.MESH.22708085
Revision H: ETH.MESH.22708086
Revision J: ETH.MESH.12830486 – ETH.MESH.12830498
Revision K: ETH.MESH.13894527
Revision L: ETH.MESH.14102819 – ETH.MESH.14102838
Revision M: ETH.MESH.13869846
Revision N: ETH.MESH.14105550
Revision P: ETH.MESH.08772169
Revision R: ETH.MESH.07905986
Revision 19: ETH.MESH.22755060 – ETH.MESH.22755086
Change Orders: ETH.MESH.22708014; ETH.MESH.22708016

Examples of Communications Referencing Changes to EMQD10:

ETH.MESH.07903697
ETH.MESH.09030721 – ETH.MESH.09030723
ETH.MESH.13905886 – ETH.MESH.13905889
ETH.MESH.09962388 – EH.MESH.09962390

VSE0007: Visual Acceptance Criteria for Blister Sealing

Defendants have previously produced all historical versions of this policy, and would refer Plaintiffs to Ben Watson's email communication to Andy Faes on July 2, 2015, attaching a final copy of versions A through N, 15 and 16 of the policy. As noted, there is no "Revision I."

Examples of Communications Referencing Changes to VSE0007:

ETH.MESH.13948436
ETH.MESH.11056963 – ETH.MESH.11056964

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C/L-E0038: Inspection of the Products Pack – TVT, TVT-AA

Revision A: ETH.MESH.22706402 - ETH.MESH.22706403
Revision B: ETH.MESH.13801519 – ETH.MESH.13801520
Revision C: ETH.MESH.04459288 – ETH.MESH.04459289
Revision D: ETH.MESH.04459290 – ETH.MESH.04459290
Revision E: ETH.MESH.04459293 – ETH.MESH.04459295
Revision F: ETH.MESH.04459296 – ETH.MESH.04459297
Revision G: ETH.MESH.04459991 – ETH.MESH.04459992
Revision H: ETH.MESH.04459993 – ETH.MESH.04459994
Revision J: ETH.MESH.04459995 – ETH.MESH.04459998
Revision K: ETH.MESH.04459999 – ETH.MESH.04460002
Revision L: ETH.MESH.04460003 – ETH.MESH.04460006
Revision M: ETH.MESH.04460007 – ETH.MESH.05560007
Revision N: ETH.MESH.04460011 – ETH.MESH.04460014
Revision P: ETH.MESH.04460015 – ETH.MESH.04460019
Revision R: ETH.MESH.04460020 – ETH.MESH.04460037
Revision T: ETH.MESH.04460038 – ETH.MESH.04460055
Revision U: ETH.MESH.04460056 – ETH.MESH.04460073
Revision V: ETH.MESH.04460074 – ETH.MESH.04460089
Revision W: ETH.MESH.04460090 – ETH.MESH.04460105
Revision Y: ETH.MESH.22706404 - ETH.MESH.22706421
Revision Z: ETH.MESH.22706422 - ETH.MESH.22706439
Revision AA: ETH.MESH.22706341 - ETH.MESH.22706359
Revision AB: ETH.MESH.13845160 – ETH.MESH.13845178
Revision AC: ETH.MESH.13819268 – ETH.MESH.13819286
Revision AD: ETH.MESH.01420129 – ETH.MESH.01420151
Revision AE: ETH.MESH.22706360 - ETH.MESH.22706380
Revision AF: ETH.MESH.13869514 – ETH.MESH.13869534
Revision AG: ETH.MESH.01416389 – ETH.MESH.01416389
Revision AH: ETH.MESH.13832784 – ETH.MESH.13832804
Revision AJ: ETH.MESH.22706381 - ETH.MESH.22706401
Revision AK: ETH.MESH.13819975 – ETH.MESH.13819975
Revision AL: ETH.MESH.13869322 – ETH.MESH.13860342
Revision AM: ETH.MESH.13869615 – ETH.MESH.13869634
Revision AN: ETH.MESH.13829588 – ETH.MESH.13829607
Revision AP: ETH.MESH.14097534 – ETH.MESH.14097553
Revision 43: ETH.MESH.13809114 – ETH.MESH.13809134
Revision 44: ETH.MESH.22706327–ETH.MESH.22706340
Change Orders: ETH.MESH.13869635 – ETH.MESH.13869638;
ETH.MESH.22706319-ETH.MESH.22706320; ETH.MESH.22706322 –
ETH.MESH.22706326

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Examples of Communications Referencing Changes to C/L-E0038:

ETH.MESH.14140324
ETH.MESH.13922935
ETH.MESH.13895181 – ETH.MESH.13895182

TAPPI 213/T437: “Dirt in Pulp – Chart Method”

It is Defendants’ understanding that TAPPI 213/T437 is a procedure created by an independent organization, and is therefore not a company operating procedure.

A version of this document, produced at ETH.MESH.22706307–
ETH.MESH.22706318, was attached to the following communication:
ETH.MESH.13990358 – ETH.MESH.13990359.

9. Inspection and Maintenance Records:

Plaintiffs requested schedules for and logs reflecting maintenance and cleaning of equipment and facilities used by Defendants for the cutting, packaging, and sterilization of TVT products.

EPG022 (ETH.MESH.14111504 – ETH.MESH.14111532) describes general equipment management at the Neuchatel facility, including preventive maintenance and work order requirements.

Equipment maintenance schedules for equipment used in the cutting and packaging of TVT products have been produced at: ETH.MESH.22796307 –
ETH.MESH.22796351.

Work order logs for equipment used in the cutting and packaging of TVT products that reflect the status of the equipment as of March 2010 have been produced at:
ETH.MESH.22734493 – ETH.MESH.227334599.

The previously produced Device History Records for the particular lots requested in Plaintiffs’ July 29, 2015 correspondence contain documentation of routine cleaning performed prior to the production of each particular lot.

Daily, weekly, monthly, and quarterly maintenance logs, as well as equipment calibration records, for sterilization equipment from Sterigenics for March 2010 have been produced at: ETH.MESH.23143930 – ETH.MESH.23143992.

Andrew N. Faes
October 6, 2015
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Sincerely,

A handwritten signature in black ink, appearing to read 'R. Bernardo', with a long horizontal flourish extending to the right.

Richard T. Bernardo

cc: Christy Jones
Ben Watson
Paul Rosenblatt
Phil Combs
Renee Baggett
Bryan Aylstock
Rich Freese